UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
NO. _____

UNITED STATES OF AMERICA, Plaintiff, v. SEASHORE DRUGS, INC., JOHN D. WAGGETT, AND BILLY W. KING II, Defendants.	)	**COMPLAINT**

The United States of America, by and through the United States Attorney for the Eastern District of North Carolina, complains and alleges as follows:

INTRODUCTION

1. For years, pharmacists at Defendant Seashore Drugs, Inc., including its owner, Defendant John D. Waggett, and its pharmacist-in-charge, Defendant Billy W. King II, unlawfully filled purported "prescriptions" in violation of the Controlled Substances Act. These "prescriptions" often involved highly-abused opioid painkillers such as oxycodone, hydrocodone, and methadone, along with other drugs like diazepam (*i.e.*, Valium), alprazolam (*i.e.*, Xanax), and carisoprodol that, when taken with opioids, heighten their potential for abuse and adverse events.

2. Over time, Seashore developed a reputation in the Wilmington pharmacy community as a place that filled the prescriptions other pharmacies

refused. Even within the pharmacy, King would often fill prescriptions that other Seashore pharmacists, no longer on shift, had previously refused to fill. And in at least one instance, when pharmacy employees reported seeing recent customers exchanging their prescription drugs on the bench in front of the pharmacy, King refused to address these concerns on the grounds that he had no control over what happened outside the pharmacy.

3. Perhaps unsurprisingly, Seashore attracted drug seekers. Individuals with known histories of prescription drug abuse filled their opioid prescriptions there. At least one customer, who routinely filled high-strength and high-quantity oxycodone prescriptions at Seashore that were written by a Florida physician, had been treated multiple times for heroin overdose. Seashore filled hundreds of prescriptions for well-known, highly abused drug cocktails written by a prescriber who eventually had his prescribing privileges suspended by the North Carolina Medical Board for keeping a patient on opioids when the patient wanted to get off of them. Multiple customers who filled their opioid prescriptions at Seashore died from prescription drug overdoses within days after Seashore handed them their pills.

4. For hundreds and hundreds of prescriptions, Seashore Drugs, Waggett, and King ignored the warning signs of illegality. As a result, they shirked their responsibility as the last line of defense between extraordinarily powerful and deadly drugs and the people seeking them. And their turn-a-blind-eye approach to pharmacy practice violated the Controlled Substances Act. The United States now seeks civil penalties and permanent injunctive relief to hold Seashore Drugs, Waggett, and King

accountable for their actions and to prevent further violations of the Controlled Substances Act.

PARTIES

5. Plaintiff is the United States of America ("United States").

6. Defendant Seashore Drugs, Inc. ("SEASHORE") is a corporation organized under the laws of North Carolina, with its principal place of business at 2059 Carolina Beach Road, Wilmington, NC 28401-7239.

7. At all times relevant to the allegations herein, SEASHORE was registered by the U.S. Drug Enforcement Administration (the "DEA") as a Retail Pharmacy under registration number AH4153401 and was engaged in the business of operating a retail pharmacy in Wilmington, North Carolina.

8. Defendant John D. Waggett ("WAGGETT") is a resident of the Eastern District of North Carolina. At all times relevant to the allegations herein, WAGGETT was a pharmacist duly licensed by the North Carolina Board of Pharmacy. WAGGETT was owner and president of SEASHORE.

9. Defendant Billy W. King II ("KING") is a resident of the Eastern District of North Carolina. At all times relevant to the allegations herein, KING was a pharmacist duly licensed by the North Carolina Board of Pharmacy. At all times relevant to the Complaint, KING was the pharmacist-in-charge at SEASHORE, and responsible for daily management of SEASHORE's pharmacy business, including the filling of prescriptions for controlled substances, subject to WAGGETT'S direction

and oversight as SEASHORE's owner and president. KING also was a signatory to SEASHORE's application for a DEA registration.

JURISDICTION AND VENUE

10. This is an action to enforce the provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* (the "CSA"). This Court has subject-matter jurisdiction over this action pursuant to 21 U.S.C. § 842(c)(1)(A), 21 U.S.C. § 882(a), 28 U.S.C. § 1345, and 28 U.S.C. § 1355.

11. Venue is proper in the Eastern District of North Carolina under 21 U.S.C. § 842(c)(1)(A), 21 U.S.C. § 843(f)(2), 28 U.S.C. § 1395(a), and 28 U.S.C. §§ 1391(b), (c), and (d).

LEGAL BACKGROUND

12. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. It is unlawful to manufacture, distribute, or dispense any controlled substance except in a manner authorized by the CSA or its implementing regulations.

13. Under the CSA, controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused.

14. Schedule II controlled substances have a currently accepted medical use in the United States, or a currently accepted medical use with severe restrictions; however, these substances also have a high potential for abuse, which may lead to

severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2). Examples of Schedule II controlled substances include opioid-based painkillers such as oxycodone, hydrocodone, and methadone.

15. Schedule III controlled substances have a potential for moderate physical dependence or high psychological dependence, but less abuse potential than Schedule II substances. *See* 21 U.S.C. § 812(b)(3). Examples of Schedule III controlled substances include buprenorphine or products containing less than 90 milligrams of codeine.

16. Schedule IV controlled substances may lead to physical or psychological dependence when abused, but the potential for abuse is less than Schedule III substances. *See* 21 U.S.C. § 812(b)(4). Examples of Schedule IV controlled substances include alprazolam (brand name Xanax), diazepam (brand name Valium), and lorazepam (brand name Ativan).

17. To prevent the diversion of controlled substances, the CSA imposes requirements for the distribution and dispensing of these drugs. Among others, all pharmacies wishing to distribute or dispense controlled substances first must register with DEA. *See* 21 U.S.C. § 822(a). Once registered, a pharmacy, as well as its agents and employees, are only permitted to distribute or dispense controlled substances to the extent authorized by their registration and in conformity with the CSA. *See* 21 U.S.C. § 822(b).

18. The CSA defines dispensing to mean delivering a controlled substance to an ultimate user (*e.g.*, a patient) by, or pursuant to a lawful order of, a practitioner

(*i.e.*, a prescription). *See* 21 U.S.C. § 802(10). Distributing means delivering a controlled substance other than by dispensing or administering. *See id.* § 802(11).

19. The rules governing the issuance and filling of prescriptions are set forth in 21 U.S.C. § 829 and 21 C.F.R. Part 1306.

20. Section 829 sets forth, among other things, the circumstances when a controlled substance may be dispensed pursuant to an oral or written prescription. Under 21 C.F.R. § 1306.04(a), a prescription for a controlled substance is valid only if it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Along with the medical practitioner issuing the prescription, a pharmacist considering whether to fill the prescription bears a "corresponding responsibility" to ensure "the proper prescribing and dispensing of controlled substances." *Id.* Any "person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.* "Person" is defined to include an individual, a corporation, a partnership, an association, and any other legal entity. 21 C.F.R. §§ 1300.01, 1306.02.

21. Under 21 C.F.R. § 1306.06, a pharmacist may only fill a controlled-substance prescription while "acting in the usual course of his professional practice." Among other things, acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations. In North Carolina, a pharmacist "shall *not* fill or refill a prescription order if, in the exercise of professional judgment, there is or reasonably may be a question regarding the order's accuracy,

validity, authenticity, or safety for the patient." 21 N.C. Admin. Code 46.1801(b) (emphasis added).

22. In assessing a prescription's legitimacy, a pharmacist looks to see whether it presents "red flags," or warning signs that create a reasonable suspicion that the prescription is not legitimate. "Red flags" may include the amount or combination of controlled substances prescribed; the abuse potential of those controlled substances; the temporal proximity to other prescriptions filled for the patient; the prescriber issuing the prescription in light of that prescriber's location, prescribing history with the patient, or general prescribing practices; or circumstances unique to the individual presenting the prescription.

23. When a "red flag" is present, a pharmacist must conduct further and sufficient inquiry to determine whether the controlled-substance prescription is legitimate. A pharmacist who fills a prescription in the face of one or more red flags without taking sufficient steps to resolve the red flags exceeds their authorization to dispense controlled substances under the CSA, and subjects the pharmacist and the pharmacy to civil penalties.

FACTUAL ALLEGATIONS

24. As a retail pharmacy, SEASHORE purchases, stores, and dispenses controlled substances. At all relevant times, SEASHORE, WAGGETT, and KING were subject to the registration and dispensing requirements of Part C of the CSA, including 21 U.S.C. § 829.

I. Defendants Systematically Ignored Red Flags When Filling Controlled-Substance Prescriptions.

25. From on or about May 11, 2015 through at least October 2019, Defendants knowingly filled prescriptions for controlled substances that presented significant red flags with respect to their medical legitimacy and/or with respect to whether they were written by a practitioner in the usual course of professional treatment. Defendants ignored and otherwise failed to take sufficient steps to resolve these red flags before filling the prescriptions.

Red Flag No. 1: Suspicious Drug Combinations

26. Prescriptions present a red flag when they prescribe combinations of drugs that are highly unlikely to serve a legitimate medical purpose and/or are known cocktails favored by drug abusers. For example, certain combinations of opioids and other controlled substances, such as benzodiazepines, muscle relaxers, sedatives, and/or stimulants, can enhance the effects of the substances, but also increase the risk of adverse events, such as overdose, to the user. For example, one well-known combination, known colloquially as the "trinity," consists of an opioid, a benzodiazepine, and a muscle relaxant (most commonly, carisoprodol).

27. Defendants repeatedly dispensed combinations of controlled substances whose medical legitimacy was suspect, including high doses of opioids combined with other opioids, benzodiazepines, muscle relaxers, or sedatives.

Red Flag No. 2: Early Fills of Schedule II and Schedule IV Drugs

28. A person's attempt to fill a prescription early—*i.e.*, before their current supply of drugs from a previous prescription is exhausted—is also a red flag that a controlled-substance prescription may not have been written for a legitimate medical purpose or in the usual course of professional treatment.

29. A review of dispensing data suggests that Defendants repeatedly dispensed controlled substances early. For example, on numerous occasions, and for multiple individuals, Defendants appear to have dispensed controlled substances more than five days early.

Red Flag No. 3: Doctor Shopping

30. A person's history of obtaining controlled substances from multiple prescribers is also a red flag that a controlled-substance prescription may not have been written for a legitimate medical purpose or in the usual course of professional treatment. For example, a physician may stop writing prescriptions for a person if the physician believes the person is abusing substances, requiring the person to seek out prescriptions from other physicians. Alternatively, a patient could move regularly from doctor to doctor to make it more difficult for any one prescriber to identify drug-seeking behavior.

31. Seeking prescriptions from multiple prescribers is colloquially referred to as "doctor shopping." Defendants had tools available to review a person's prescription history, including prescriber information, through North Carolina's Controlled Substance Reporting System.

32. Defendants nevertheless repeatedly dispensed opioids and other controlled substances to doctor-shopping individuals, including people who had received controlled-substance prescriptions from ten or more prescribers in the previous five years, and to at least one person who had received controlled-substance prescriptions from twenty-six separate prescribers during the previous five years.

Red Flag No. 4: Use of Distant Prescriber

33. A person traveling an unusually long distance from their home address and/or their prescriber's office to fill a prescription or regularly seeking to fill prescriptions issued by a distant, out-of-state prescriber can be a red flag that the prescription was not written for a legitimate medical purpose or in the usual course of professional practice.

34. Defendants repeatedly dispensed controlled substances to at least two individuals who regularly obtained monthly prescriptions for high quantities and doses of opioids written by a Florida prescriber located hundreds of miles away from SEASHORE.

Red Flag No. 5: Pattern Prescribing

35. A single prescriber who repeatedly issues prescriptions for the same drug or drug combinations to multiple people also raises a red flag that the prescriptions may not have been written for a legitimate medical purpose or in the usual course of professional treatment. This practice is colloquially referred to as "pattern prescribing."

36. Defendants repeatedly dispensed the same drug and/or similar drug combinations prescribed by the same practitioner for multiple individuals (*i.e.*, pattern prescribing), including for individuals residing at the same address.

Red Flag No. 6: Excessive Quantities/Doses

37. The dosage, quantity, and/or strength of controlled substances prescribed by a prescription can present a red flag when those extremely high and such extremely high doses continue for extensive periods of time. For example, the Centers for Disease Control and Prevention ("CDC") urge caution when an individual receives an opioid dosage greater than 90 morphine milligram equivalents ("MME") per day. Daily dosages that significantly exceed this guideline, particularly when presented for extensive periods of time, can present a red flag that the prescription is not issued for a legitimate medical purpose.

38. Defendants repeatedly dispensed extremely high doses of opioids to patients every month for years on end—often more than double or triple the CDC guideline for appropriate daily MME.

Red Flag No. 7: Family Members & Individuals Residing at Same Address

39. The presentation of prescriptions for similar controlled substances by members of the same family or by individuals residing at the same address is also a red flag that the prescriptions may not have been written for a legitimate medical purpose or in the usual course of professional treatment.

40. Defendants repeatedly dispensed controlled substances, including many of the same drugs, to individuals of the same family and/or individuals sharing a common address.

Red Flag No. 8: Cash Payments

41. An individual with health insurance who nonetheless seeks to pay in cash for a controlled substance prescription is a red flag that the prescription may not have been written for a legitimate medical purpose or in the usual course of professional treatment. Health insurance companies regularly perform a drug utilization review when deciding whether to pay for a prescription. This review includes a therapeutic component to ensure the prescription is medically appropriate. Cash payment, however, bypasses the insurance company's drug utilization review.

42. Defendants dispensed controlled substances to at least one individual who paid in cash despite paying for other prescriptions through health insurance.

II. Many Individuals Presented Multiple Red Flags

43. In many cases, the foregoing red flags were not presented to Defendants in isolated fashion. Rather, Defendants ignored numerous red flags presented by the same person or prescription. The following examples illustrate the extent to which Defendants repeatedly failed to resolve multiple red flags in filling prescriptions for powerful and often-abused controlled substances.

Individuals A and B

44. SEASHORE filled 238 controlled-substance prescriptions for Individual A between January 10, 2013 and January 17, 2019.[1] Individual A's prescriptions raised numerous red flags, including extensive numbers of prescriptions written by a distant out-of-state doctor, extremely high quantities and strengths of opioids, suspicious drug combinations, doctor shopping, and the filling of opioids for Individual A's family member—namely, one of Individual A's parents (Individual B), who resided at the same address as Individual A.

45. More than half (142) of the prescriptions SEASHORE filled for Individual A were written by a Florida-based doctor (the "Florida Prescriber"), located hundreds of miles away from SEASHORE. These prescriptions were nevertheless routinely filled at SEASHORE each month for consecutive months at a time until September 2016, when Individual A stopped filling prescriptions from the Florida Prescriber.

46. The prescriptions written by the Florida Prescriber and regularly filled by SEASHORE also consisted of extremely high quantities and strengths of opioids. For Individual A, the Florida Prescriber consistently prescribed 120 tablets of 30-mg oxycodone together with 60 tablets of extended-release OxyContin (either 40-mg strength or 60-mg strength). The combined daily MME for these opioids equaled 300 or more—nearly four times the CDC guideline for caution. In total, between 2013

[1] This suit seeks penalties only for violations going back to May 11, 2015. However, the pattern of fills by Defendants before May 11, 2015 is relevant to their pattern of conduct, their awareness of red flags, and the information to which they had access when assessing red flags for prescriptions filled after May 11, 2015.

and 2019, SEASHORE dispensed more than 12,000 opioid pills to Individual A—with more than half of those pills (6,450) being 30-mg oxycodone and an additional 2,580 pills being 60-mg OxyContin.

47. Individual A also exhibited signs of doctor shopping. In addition to the fact that thirteen separate prescribers prescribed Individual A controlled substances between January 2013 and January 2019, there were several instances where Individual A received overlapping opioids prescriptions consistent with duplicative therapy. For instance, for three months in 2015, SEASHORE filled 30-mg oxycodone and 60-mg OxyContin prescriptions written by the Florida Prescriber in a given month, and then, approximately two weeks later, SEASHORE filled a *separate* prescription, written by a Wilmington, North Carolina physician, for 120 tablets of 10-mg hydrocodone/325-mg acetaminophen—another potent and addictive opioid. Thus, during these months, the additional, intervening hydrocodone pushed Individual A's daily MME to 400. In other instances, there would be months-long lapses in prescriptions by the Florida Prescriber, only to have another local prescriber prescribe similar, high-strength combinations of opioids.

48. In addition to receiving high quantities and strengths of opioids from multiple different physicians, Individual A often also received opioids in combination with other potentiating drugs—namely, alprazolam (*i.e.*, Xanax). In addition, on at least two occasions, SEASHORE also dispensed carisoprodol, a muscle-relaxer that forms part of the well-known "trinity" cocktail regularly abused by drug seekers. Nevertheless, SEASHORE filled these prescriptions on a near-monthly basis. For

example, *on a single day in 2014*, SEASHORE dispensed to Individual A 180 tablets of 30-mg oxycodone, 60 tablets of 60-mg OxyContin, 120 tablets of 0.5-mg alprazolam, and 90 tablets of 350-mg carisoprodol. The daily MME for this combination totaled 450—five times the CDC guideline for caution—*before* considering the potentiating effects of the alprazolam and carisoprodol.

49. In addition, Individual A routinely presented his prescriptions early—that is, before the previous month's supply of drugs was exhausted—and SEASHORE filled them. Specifically, SEASHORE filled 48 prescriptions for oxycodone or OxyContin one-to-three days early, two prescriptions five days early, one prescription six days early, and one prescription *twenty* days early. The consistent early filling over time resulted in Individual A receiving a far greater number of opioids than the actual amount Individual A should have received if taking the drugs as prescribed. For instance, during the period of January 15, 2015 through January 14, 2020, Individual A received thirteen month-long supplies of 30-mg oxycodone and 60-mg OxyContin when Individual A should have received no more than twelve. This pattern was repeated through SEASHORE's filling history for Individual A.

50. Unsurprisingly from the red flags presented, there is also evidence that Individual A suffered from opioid addiction; Individual A received medical treatment on multiple occasions for overdosing on heroin.

51. Compounding these problems, SEASHORE also filled numerous prescriptions for Individual B, who is one of Individual A's parents and, for almost all

of the prescriptions SEASHORE filled for the two of them, is listed as residing at the same address as Individual A.

52. SEASHORE filled 367 controlled-substance prescriptions for Individual B between January 2013 and October 2019. Like the prescriptions for Individual A, a number of these prescriptions raised red flags in their own right.

53. First, dozens of Individual B's prescriptions were written by the same Florida Prescriber who wrote so many of Individual A's prescriptions.

54. Second, in many instances, the timing of these prescriptions were extremely suspicious in light of other prescriptions SEASHORE filled for Individual B from other prescribers. For example, on multiple occasions, these Florida-Prescriber prescriptions were filled by SEASHORE the very same day that they were purported to have been written, only to have SEASHORE fill another prescription for similar or potentiating drugs purportedly written by a Wilmington prescriber just days later. For example, on September 14, 2015, SEASHORE dispensed thirty-day supplies of tramadol (50-mg), oxycodone (10-mg), and carisoprodol (350-mg) to Individual B based on prescriptions purportedly written on September 14, 2015 by a Wilmington prescriber. Three days later, on September 17, 2015, SEASHORE dispensed *another* thirty-day supply of oxycodone (20-mg) to Individual B based on a prescription purportedly written by the Florida prescriber the same day (September 17, 2015). Then, the very next day (September 18, 2015), SEASHORE dispensed the benzodiazepine clonazepam (.5-mg) to Individual B based on a prescription purportedly written by the Wilmington prescriber the same day (September 18,

2015). The timing of these prescriptions, particularly the prescription of the Florida Prescriber for additional oxycodone wedged between two prescriptions by the Wilmington prescriber, raised serious red flags about the legitimacy of the prescriptions.

55. The strength and quantities of opioids dispensed by SEASHORE to Individual B also presented significant red flags. Combinations of 30-mg or 20-mg oxycodone and 40-mg or 20-mg OxyContin were common place. Nearly every month for years, SEASHORE dispensed quantities of opioids to Individual B that exceeded twice the CDC's 90 MME guideline for caution. In some months, SEASHORE dispensed to Individual B opioids totaling 390 daily MME—more than four times the CDC guideline for caution.

56. Furthermore, as was the case for Individual A, SEASHORE consistently dispensed opioids in conjunction with other potentiating drugs, the combinations of which were known to be abused.

57. SEASHORE dispensed the "trinity" combination—an opioid (oxycodone), a benzodiazepine (alprazolam or clonazepam), and a muscle-relaxer (carisoprodol)—to Individual B on numerous occasions. In many instances, the drugs forming these cocktails were dispensed just days apart or all on the same day. For example, on December 8, 2015, SEASHORE dispensed tramadol, clonazepam, carisoprodol, and the nerve-pain medication pregabalin to Individual B. Three days later, on December 11, 2015, SEASHORE dispensed an additional 120 pills of 20-mg oxycodone and 60 pills of 30-mg OxyContin to Individual B. SEASHORE followed

the exact same pattern the following month, dispensing the first four drugs on January 5, 2016 and the second two potent opioids on January 7. On April 5, 2016 and again on May 4, 2016, SEASHORE dispensed a five-drug cocktail to Individual B—20-mg oxycodone, 30-mg OxyContin, 0.5-mg clonazepam, 350-mg carisoprodol, and 100-mg pregablin. These highly abused drug combinations—particularly as they were repeated month after month for years—raised serious red flags about the medical legitimacy of these prescriptions.

58. Furthermore, as was the case for Individual A, SEASHORE routinely filled opioid and other prescriptions early. Forty (40) oxycodone or OxyContin prescription were filled one-to-three days early, five such prescriptions were filled four-to-six day early, and one was filled ten days early. The routine and consistent early filling of prescriptions led to Individual B receiving more opioids than she otherwise would have received had these prescriptions not been filled early.

59. In addition, a review of SEASHORE's dispensing histories for Individuals A and B reveals that their use of the same pharmacy was not, as one might expect, purely for the sake of convenience, with them having prescriptions routinely filled the same day. Indeed, SEASHORE did not regularly fill prescriptions for them the same day. Rather, a review of the history shows SEASHORE dispensing a steady stream of opioids and other potentiating controlled substances over the course of just about any given month.

60. For example, in July 2015, SEASHORE dispensed controlled substances to Individual A or Individual B on seven different dates—July 2 (oxycodone,

OxyContin), July 10 (pregabalin), July 11 (oxycodone, alprazolam), July 20 (clonazepam), July 23 (oxycodone, pregabalin, the stimulant armodafinil), July 24 (OxyContin), and July 30 (oxycodone, OxyContin). In June 2016, SEASHORE dispensed controlled substances to Individual A or Individual B on eight different dates—June 1 (oxycodone, OxyContin, clonazepam, pregabalin), June 2 (oxycodone, OxyContin), June 17 (carisoprodol, pregabalin), June 20 (armodanifil), June 23 (oxycodone), June 25 (alprazolam), June 29 (carisoprodol), and June 30 (oxycodone, OxyContin, clonazepamn, pregabalin).

61. SEASHORE dispensed controlled substances to Individual A and Individual B without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented for filling at the pharmacy in violation of the CSA.

Individual C

62. Between May 15, 2015 and September 30, 2019, SEASHORE filled 209 controlled-substance prescriptions for Individual C, an individual in their mid- to late-thirties. Individual C's prescriptions raised numerous red flags, including extremely high quantities and strengths of opioids, suspicious drug combinations, and routine early fills.

63. SEASHORE routinely filled prescriptions for Individual C consisting of extremely high quantities and strengths of opioids. Nearly every month for multiple years, SEASHORE dispensed combinations of 15-mg oxycodone, 60-mg extended release morphine, and 100-mg tapentadol (another opioid marketed under the brand

name Nucynta). Every single month between May 2015 and March 2016, SEASHORE dispensed this combination of opioids in such quantities that the resulting average daily MME was 330—nearly four times the CDC's guideline for caution.

64. SEASHORE also routinely dispensed these opioids in combination with other potentiating drugs known to be highly abused. Indeed, for *twenty-two* consecutive months, SEASHORE dispensed to Individual C the following five-drug cocktail, which included the drugs commonly known as the "trinity": three opioids (oxycodone, morphine, and tapentadol), a benzodiazepine (clonazepam), and a muscle-relaxant (carisoprodol). For each of these twenty-two instances, all five drugs were dispensed the same day. Thereafter, SEASHORE continued to dispense a similar four-drug cocktail to Individual C (*i.e.*, the trinity plus an opioid), consisting of oxycodone, morphine, clonazepam, and carisoprodol for several more months, with the drugs almost always being dispensed together on the same day. Indeed, the trinity combination, for months on end, dominated the dispensing history for Individual C—in total, Individual C received the combination 52 times between May 2015 and September 2019.

65. Furthermore, SEASHORE routinely filled prescriptions for Individual C early. Between 2013 and 2019, ninety-one controlled substances prescriptions were filled one-to-three days early, resulting, over time, in substantial quantities of "extra" opioids and other drugs being dispensed to Individual C.

66. Of the 209 prescriptions referenced above between May 2015 and September 2019, a Wilmington, North Carolina prescriber ("Prescriber 1") wrote sixty-one prescriptions, and other practitioners affiliated with Prescriber 1's office wrote a substantial number of the other prescriptions. On June 12, 2018, Prescriber 1's controlled-substance prescribing privileges were suspended by Consent Order of the North Carolina Medical Board due to Prescriber 1's prescribing conduct. Specifically, much like he did for Individual C, Prescriber 1 was found to have maintained a different patient "on chronic narcotic and benzodiazepine therapy with minimal attempts at alternative treatments," including prescribing "multiple controlled substances simultaneously and concomitantly with benzodiazepines." That patient was ultimately involuntarily admitted for addiction detoxification with diagnoses of Opioid Use Disorder, Severe, and Benzodiazepine Use Disorder. Prescriber 1 acknowledged in the Consent Order that his conduct constituted a departure from or failure to conform to the standards of acceptable and prevailing medical practice.

67. Nevertheless, even after Prescriber 1 lost his prescribing privileges after June 11, 2018, Individual C continued to obtain—and SEASHORE continued to dispense—drug cocktails substantially similar to the drugs Prescriber 1 had been routinely prescribing to Individual C before Prescriber 1's privileges were suspended. For instance, on April 6, May 4, and June 1, 2018, SEASHORE filled prescriptions for Individual C that were written by Prescriber 1 and consisted of combinations of oxycodone, morphine, and carisoprodol. During the next several months, even though

Prescriber 1 had lost his prescribing privileges, SEASHORE continued to fill the same combination of drugs, with prescriptions largely being written by a nurse practitioner under Prescriber 1's supervision or a different physician in Prescriber 1's office. SEASHORE continued to fill these prescriptions, with no documentation noted regarding Prescriber 1's licensing issues or continued pattern prescribing.

68. SEASHORE dispensed controlled substances to Individual C without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented for filling at the pharmacy in violation of the CSA.

Individual D

69. Between May 15, 2015 through September 30, 2019, SEASHORE filled 252 controlled-substance prescriptions for Individual D. Individual D's prescriptions repeatedly raised red flags, including extremely high quantities and strengths of opioids and suspicious drug combinations.

70. SEASHORE routinely filled prescriptions for Individual D consisting of extremely high quantities and strengths of opioids. Nearly every month between May 2015 and September 2017, SEASHORE dispensed a combination of opioids—methadone and oxycodone—that equated to an average dosage exceeding 300 MME per day. That dosage is more than three times the level of 90 MME per day at which the CDC recommends caution and greater justification for dispensing. Yet SEASHORE's records contain no such justification. And beyond the dosage, the quantities dispensed were staggering. All told from May 2015 to September 2019,

SEASHORE dispensed nearly *twenty thousand* tablets of opioids—methadone and oxycodone—to Individual D.

71. In addition to the potent opioids dispensed, SEASHORE routinely dispensed these opioids to Individual D in combination with other potentiating drugs known to be highly abused. On a monthly basis, SEASHORE also dispensed the benzodiazepine alprazolam (*i.e.*, Xanax) and the stimulant dextroamphetamine/amphetamine. When taken with opioids, a benzodiazepine like alprazolam enhances the euphoric effect of the opioid. Benzodiazepines are also, like opioids, central nervous system depressants. Both the CDC and the U.S. Food and Drug Administration ("FDA") have noted the heightened risk of respiratory depression and overdose when taking opioids and benzodiazepines concurrently. Furthermore, taking a stimulant in combination with these drugs can lead a user to take a greater dose of depressants to achieve the desired effect. Thus, Individual D's combination of an opioid, a benzodiazepine, and a stimulant potentiated the effects of each individual medication and increased the risk of overdose. Yet SEASHORE's records again did not demonstrate that due diligence was conducted to justify for such a cocktail.

72. SEASHORE dispensed controlled substances to Individual D without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented for filling at the pharmacy in violation of the CSA.

Individual E

73. Between May 15, 2015 and May 31, 2019, SEASHORE filled 138 controlled-substance prescriptions for Individual E. Individual E's prescriptions repeatedly raised red flags, including high quantities and strengths of opioids and suspicious drug combinations, as well as early fills.

74. SEASHORE routinely filled prescriptions for Individual E consisting of high quantities and strengths of opioids. During an 18-month period, SEASHORE dispensed two dozen opioid prescriptions with an average dosage at or exceeding the 90 MME level at which the CDC recommends caution and greater justification for dispensing. Yet SEASHORE's records detail no such justification.

75. SEASHORE also routinely dispensed these opioids to Individual E in combination with other potentiating drugs known to be highly abused. Month after month in 2015 and 2016, SEASHORE dispensed to Individual E oxycodone, alprazolam, and carisoprodol—three drugs that, collectively, comprise one version of the well-known "trinity" cocktail regularly abused by drug seekers. Although this drug combination increased Individual E's risk of overdose, SEASHORE's records did not demonstrate that due diligence was conducted to justify such a cocktail.

76. In mid-to-late 2017, SEASHORE dispensed Suboxone to Individual E. Because Suboxone is indicated for the treatment of opioid dependence, its prescribing to Individual E indicates treatment for substance abuse disorder. However, in December 2017, Individual E switched prescribers, stopped receiving Suboxone, and started receiving prescriptions for opioids again. And again SEASHORE began

dispensing those opioids without comment to an individual it had reason to know had suffered from a substance abuse disorder.

77. Furthermore, SEASHORE frequently filled prescriptions for Individual E early. Between 2014 and 2019, 15 controlled substances prescriptions were filled five to fourteen days early, resulting in substantial quantities of "extra" opioids and other drugs being dispensed to Individual E.

78. SEASHORE dispensed controlled substances to Individual E without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented for filling at the pharmacy in violation of the CSA.

Individuals F and G

79. In addition to the foregoing, SEASHORE dispensed opioids and other controlled substances in the face of red flags to individuals who had histories of abusing prescription medications and who eventually died from overdosing on the drugs SEASHORE dispensed to them.

80. For example, on the morning of June 23, 2017, Individual F, fifty-five years old at the time, was found dead. An autopsy report of Individual F determined the cause of death to be a combined drug overdose of oxycodone, alprazolam, and gabapentin. Furthermore, Individual F's autopsy report noted a history of alprazolam and oxycodone abuse, as well as several overdoses.

81. Over a four-year period between 2013 and 2017, SEASHORE had filled numerous oxycodone prescriptions for Individual F, as well as prescriptions for the benzodiazepines alprazolam and lorazepam.

82. SEASHORE filled these prescriptions notwithstanding red flags—in particular, signs of both doctor shopping and pharmacy shopping. In 2017 alone, Individual F filled controlled substances at five different pharmacies (including SEASHORE). Between 2013 and 2017, SEASHORE filled prescriptions for Individual F written by seven separate physicians. During 2016 and 2017, Individual F was regularly prescribed alprazolam by one prescriber and oxycodone by another, but SEASHORE regularly filled both (including on the same day or just days apart). In the approximate year-long period preceding Individual F's death, SEASHORE dispensed eight separate oxycodone-acetaminophen prescriptions and four separate alprazolam prescriptions.

83. On June 19, 2017, just three days before Individual F was found dead, SEASHORE dispensed 90 pills of oxycodone-acetaminophen. The very next day (and just two days before Individual F was found dead), SEASHORE dispensed 90 pills of alprazolam. These were the two substances determined to have contributed to Individual F's overdose death.

84. Similarly, Individual G, forty-eight years old, was found dead in bed on October 7, 2018. An autopsy report of Individual G determined the cause of death to be a combined drug overdose of hydrocodone and diphenhydramine (brand name Benadryl). Clonazepam was noted in Individual G's bloodstream and was also believed to have possibly contributed to Individual G's death. Furthermore, Individual G's autopsy report noted a history of prescription drug abuse.

85. Over an approximate two-year period between 2016 and 2018, SEASHORE filled more than eighty controlled-substance prescriptions for Individual G, including numerous prescriptions for hydrocodone and clonazepam, as well as other opioids (such as oxycodone) and benzodiazepines (alprazolam, diazepam, and lorazepam).

86. SEASHORE filled these prescriptions notwithstanding red flags—in particular, doctor shopping, pharmacy shopping, early filling, duplicative therapy, and cash payments. In 2017 and 2018 alone, SEASHORE filled controlled substances for Individual G written by twenty-four separate physicians. Individual G utilized more than five different pharmacies to fill controlled substances between 2013 and 2018. For one two-month period, SEASHORE dispensed seven separate hydrocodone-acetaminophen prescriptions of various strengths, written by four separate providers, all paid in cash. On at least one occasion, SEASHORE dispensed opioids paid for by cash just three days after Individual G obtained opioids from a different pharmacy using insurance. Furthermore, between 2016 and 2018 alone, Individual G filled more than a dozen prescriptions early, including one hydrocodone-acetaminophen prescription seven days early and another eleven days early.

87. On October 2, 2018, just five days before Individual G was found dead from an overdose, SEASHORE dispensed 60 units of clonazepam. On October 6, 2018, SEASHORE dispensed 120 units of hydrocodone-acetaminophen. Hydrocodone was one of the two drugs determined to have caused Individual G's overdose death, with clonazepam noted as a contributing factor.

88. SEASHORE dispensed controlled substances to Individuals F and G without taking necessary and sufficient steps to resolve the red flags raised by the prescriptions presented for filling at the pharmacy in violation of the CSA.

III. Additional Evidence of Unlawful Filling of Controlled-Substance Prescriptions.

89. Some SEASHORE pharmacists recognized the red flags associated with controlled-substance prescriptions being presented by individuals and sometimes refused to fill them. Those customers, however, would return when KING was working and KING would fill them—*i.e.*, the same prescription that another SEASHORE pharmacist refused to fill. In some instances, pharmacist technicians would inform KING of the earlier refusal, but KING would fill the prescription anyway.

90. On at least one other occasion, SEASHORE customers were observed exchanging drugs outside the pharmacy. Although these observations were reported to KING, KING did not take actions to address these concerns, and the customers were allowed to continue filling prescriptions at SEASHORE.

CIVIL PENALTY LIABILITY
21 U.S.C. § 842(a)(1)

91. The United States re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

92. 21 U.S.C. § 842(a)(1) makes it unlawful for any person subject to Part C of the CSA to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829. As a DEA registrant, owner-pharmacist, and pharmacist-in-charge of a

registrant dispensing controlled substances, respectively, SEASHORE, WAGGETT, and KING are subject to Part C of the CSA.

93. Defendants violated 21 U.S.C. § 829 by filling prescriptions for Schedule II, III, or IV controlled substances that also were prescription drugs under the Federal Food, Drug, and Cosmetic Act, outside the usual course of pharmacy practice and not in compliance with their "corresponding responsibility." 21 C.F.R. §§ 1306.04 and 1306.06.

94. Namely, in an amount to be determined at trial, and upon information and belief, Defendants filled prescriptions without resolving one or more red flags indicating that such prescriptions were not written for a legitimate medical purpose or in the usual course of professional treatment.

95. Under 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5, each violation of 21 U.S.C. § 842(a)(1) subjects Defendants to a civil penalty of not more than $25,000.00 for violations occurring on or before November 2, 2015, and not more than $64,820.00 for violations occurring after November 2, 2015.

PERMANENT INJUNCTIVE RELIEF
21 U.S.C. §§ 843(f)(1) and 882(a)

96. The United States re-alleges and incorporates by reference the foregoing paragraphs as if fully set forth herein.

97. Under 21 U.S.C. § 843(f), the Attorney General of the United States is authorized to seek appropriate declaratory or injunctive relief relating to violations of 21 U.S.C. § 842. More broadly, 21 U.S.C. § 882(a) provides for any violation of the CSA to be enjoined.

98. Based on the violations set forth herein and Defendants' years-long pattern of conduct, the United States requests that the Court enter a permanent injunction (i) prohibiting Defendants from administering, dispensing, or distributing any controlled substance; (ii) prohibiting WAGGETT and KING from serving as a manager, owner, operator, or pharmacist-in-charge of any entity, including a pharmacy, that administers, dispenses, or distributes controlled substances; (iii) prohibiting WAGGETT and KING from applying for or seeking renewal of any DEA Certificate of Registration on their behalf or on behalf of any corporate entity; and (iv) any other injunctive relief the Court deems appropriate and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court enter judgment in favor of the United States and against Defendants as follows:

1. Impose civil penalties up to the maximum amount allowed by law for each violation of 21 U.S.C. § 842(a)(1) committed by Defendants;

2. Enter a permanent injunction (i) prohibiting Defendants from administering, dispensing, or distributing any controlled substance; (ii) prohibiting WAGGETT and KING from serving as a manager, owner, operator, or pharmacist-in-charge of any entity, including a pharmacy, that administers, dispenses, or distributes controlled substances; and (iii) prohibiting WAGGETT and KING from applying for or seeking renewal of any DEA Certificate of Registration on their behalf or on behalf of any corporate entity;

3. Award the costs associated with the investigation, prosecution, and collection of the penalties and other relief in this matter; and

4. Award any other relief deemed just by the Court.

Respectfully submitted this the 30th day of October, 2020.

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